REMARKS

The currently claimed invention comprises antibodies or antibody fragments that are capable of detecting active hPTH, as well as immunological methods for using these antibodies and antibody fragments and kits containing these antibodies and antibody fragments. The present invention is capable of detecting active hPTH as opposed to inactive hPTH. It is important in measuring the amount of hPTH to determine the health status of humans that one be certain that the hPTH being measured is active, having biological activity, and is not inactive hPTH that may be a metabolic by-product. Inactive hPTH does not provide accurate information about the active hormone status of the human. For example, hPTH is known to play an important role in the metabolism of calcium.

In the current response, Claims 6-21 have been cancelled without prejudice. Claims 22 through 40 have been added and are currently pending in this application. Support for these newly added claims can be found throughout the specification. No new matter has been added.

This response is accompanied by a Petition for a one-month extension of time and a check for $55 to cover the fee for the one month extension. No additional fees are believed due; however, the Commissioner is hereby authorized to charge any additional fees required under 37 CFR §1.16, or credit any overpayment, to Account No. 10-1215.

CLAIM OBJECTIONS

The Examiner has objected to Claims 7-17 stating that the Claims contained informalities. Claims 7-17 have been canceled herein, rendering these rejections moot.

REJECTIONS UNDER 35 U.S.C. §112, FIRST PARAGRAPH

The Examiner has rejected Claims 7-21 under 35 U.S.C. § 112, first paragraph, stating that the Specification does not enable a person skilled in the art to make and/or use the invention commensurate in scope with the claims. Claims 7-21 have been canceled herein. Applicants submit that newly added Claims 22-40 are enabled by the specification for the following reasons.

Applicants respectfully submit that the specification is enabling of the scope of the now pending claims which are drawn to antibodies or antibody fragments and methods of using the same in binding assays. While the Examiner stated that the specification was enabling for antibodies raised against the disclosed peptides and for methods of detecting hPTH peptides comprising contacting a sample with the antibodies or fragments thereof and assaying for binding, the Examiner also stated that it is hard to theorize how such antibodies would be capable of distinguishing between active and inactive forms of hPTH. In so stating, the Examiner has characterized hPTH fragments (such as hPTH(1-37)) as active and hPTH peptides (such as hPTH(1-84)) as inactive. However, Applicants submit that both the hPTH fragments (such as hPTH(1-37)) and the hPTH peptides (such as hPTH(1-84)) are active. Applicants further submit that the inactive forms of hPTH are those that have lost the first two amino acids. The specification, at page 1 second paragraph, states that "...upon loss of the first amino acid, serine, the activity significantly decreases and is lost completely without the first two amino acids, serine and valine." At page 6 second full paragraph, the specification continues by stating "[a]ntibodies are formed, binding to the first amino acids of the N-terminus. Deficiency of only two amino acids gives rise to a substantial loss in affinity. Because these amino acids are indispensable for the biological activity to arise, it is possible by using the peptides of the invention to obtain antibodies recognizing only hPTH and fragments thereof which are biologically active." Therefore, by enabling the production of antibodies binding the first two amino acids of the N-terminus, the

specification enables the production of antibodies capable of detecting active hPTH.

Further, the specification, at page 6 third full paragraph, states that antibodies can be raised against the peptides at the C-terminal region of hPTH (1-37) and that these antibodies bind regions on hPTH that are separated from each other by such a far distance that no steric hindrance is present which would prevent simultaneous binding of two antibodies.

Applicants submit that by enabling the raising of antibodies against the disclosed peptides sequences containing the first two amino acids of the N-terminus the Applicants' disclosure enables one skilled in the art to detect active hPTH.

REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

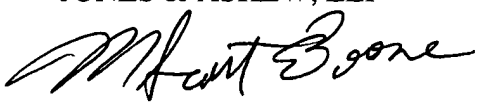
The Examiner rejected Claims 7-21 as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicants regards as their invention. The Examiner further rejected Claims 17-21 as not achieving the goal set forth in the preamble. Applicants have canceled Claims 7-21 herein, thereby making the rejection moot. Applicants therefore respectfully request that the rejections under 35 U.S.C. § 112, second paragraph, be withdrawn. Applicants thank the Examiner for her suggested claim language. The suggestions have been incorporated into the newly added claims.

CONCLUSION

In light of the amendments and the above remarks, Applicants are of the opinion that the Office Action has been completely responded to and that the pending claims are now in condition for allowance. Such action is respectfully requested. If the Examiner believes any informalities remain in the application which may be corrected by Examiner's amendment, or if there are any other issues which can be resolved by telephone interview, a telephone call to the undersigned attorney at (404) 949-2400 is respectfully solicited.

Respectfully submitted,

JONES & ASKEW, LLP



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